

### **REMARKS**

Claims 1-27 are pending. Claims 1-18, 21-22, and 24-27 have been rejected. Claims 19, 20, and 23 are objected to.

Claims 1, 13, 14, 16, 17, and 20-21 have been amended. Claims 7, 18, and 24-27 have been cancelled. Claims 28-33 are new. No new matter has been added by these amendments and additions.

### **Interview**

Applicants thank the Examiner for the discussion held on 16 November 2004 between the Examiner and Applicants' representative Gary Quick, during which the rejections and possible amendments were discussed. No agreement was reached.

### **Claim Rejections over Highgate**

Claims 1, 3, 4, 25, and 26 have been rejected under 35 U.S.C. §102(b) in view of Highgate et al., U.S. Patent No. 4,565,722 ("Highgate"). Claims 2, 5-11, 24, and 27 have been rejected under 35 U.S.C. §103(a) in view of Highgate. Claim 12 has been rejected under 35 U.S.C. §103(a) in view of Highgate and Rawls, U.S. Patent No. 5,527,181 ("Rawls").

Highgate discusses shaped polymeric compositions that can absorb liquid. However, Highgate does not disclose any material or method for moving teeth, and the compositions and shapes disclosed are not suggested for use in any orthodontic purpose at all. In fact, the only shape discussed for use in even a dental application is a wedge shape plug that swells to fill a tooth cavity after removing the nerve. (col. 4, lines 58-60). However, many materials may swell to fill a cavity, such as hydraulic cements. However, no one has suggested using such a material to move teeth apart. Highgate also does not suggest using a material to move teeth apart, or to move anything at all.

The other shapes shown and discussed in Highgate are also specified for use in certain other applications. For example, discs for use as breast implants, or a straight insert with ends that swell after contact with body fluids for blocking passages, specifically useful as a Fallopian

Tube closure (col. 5, lines 23-28). Highgate does not disclose or suggest that these other shapes would be suitable for orthodontic or dental use. In fact, there is no mention or discussion in Highgate about use of any material or shape as an orthodontic separator. Instead, the shapes are directed to specific associated applications, such as filling or closing body cavities, openings, or vessels, or being used as implants.

Rawls discusses a dental wedge comprising a rigid core and an elastic outer component used to assist in maintaining a band tightly against a tooth surface for fillings. Rawls also discusses adding a radio-opaque element, useful in case of aspiration.

Claim 1 has been amended and now recites an orthodontic separator in the shape of an o-ring or dog bone. Support for the amendment to claim 1 may be found, for example, at page 3, lines 18-20 and FIGs. 1A-1D. These shapes are clearly stated as the preferred shapes at page 3, lines 18-20 of the application and are particularly shown in FIGS 1A, 1B, 1C, and 1D. These shapes are preferred because of the function of an orthodontic separator, as discussed in the Declaration of Tsi-Zong Tzou (attached). The orthodontic separator is intended to stay in place between the teeth in order to separate the teeth, and may be required to stay in place up to one week or longer. During this time, the patient will be active, and the separator must withstand body movement and motion, eating, talking, etc., along with all of the associated forces. Thus, it is important that the orthodontic separator be placed in and remains in the proper position, and it is desirable that the teeth maintain proper alignment during the separation.

Orthodontic separators increase the space between adjacent teeth before fitting orthodontic bands, as described in paragraph 7 of the Tsi-Zong Tzou declaration. Generally, teeth come together at a contact point, near the middle of each tooth. Thus, the teeth will be closest together, and perhaps touching, at the contact point, while other locations between the teeth are further apart. The separator is more likely to remain in place and not fall out over an extended time of a week or more, and better maintain the proper alignment of the teeth, when the separator conforms to the space between adjacent teeth such that the separation pressure is on a larger area of each tooth than just the contact point.

The o-ring and dog bone configurations are preferred for orthodontic separators because they can be inserted between the teeth in a manner that allows tight contact between the separator

and surfaces of the teeth other than just the contact point, as discussed in paragraphs 9 & 10 of the Tsi-Zong Tzou declaration. The shape of the separator assists in locating the separator with correct placement, and assists in maintaining the separator in the correct location through the lengthy separation time. The shape of the separator also ensures that pressure is placed on a larger surface of the tooth than just the contact point. The pressure, distributed more evenly over a greater area, assists the effectiveness of the separator, and helps minimize rotation or other effects that could lead to tooth misalignment.

In contrast, the use of a dental wedge shape for an orthodontic separator is inferior for several reasons, including: (1) the wedge shape does not conform to the interproximal space between adjacent teeth; (2) the wedge shape applies force on one side of the arch of the teeth and its reaction force tends to push the wedge out; (3) the uneven pressure exerted by a wedge shape may lead to rotation of a tooth during separation; and (4) the wedge may touch the surrounding soft tissues causing irritation over the extended period of time of separating teeth. These problems and limitations are discussed in paragraph 13 of the Tsi-Zong Tzou declaration.

The only shape proposed for dental use (but not orthodontic use) in Highgate is a wedge shape. There is no suggestion that the other shapes described would be considered for dental use, nor any indication that such shapes would even be useful or suitable. In particular, there is no suggestion for using the Fallopian tube straight insert with swelling ends in a dental application. Rawls only discusses the use of a single shape – a wedge shape for use during a cavity filling procedure.

Neither reference teaches, discloses, or suggests the use of a separator, wherein the separator is in the shape of an o-ring or dog bone. These shapes have particular benefits, as described above and as discussed in the Tsi-Zong Tzou declaration. The Federal Circuit has stated that it is not necessary for “evidence and arguments responsive to the obviousness rejection to be within his specification in order to be considered.” *In re Chu*, 66 F.3d 292, (Fed. Cir. 1995).

As neither shape is taught, described, or suggested by the references, claim 1 is both novel and nonobvious over Highgate and Rawls. Therefore, applicants respectfully request withdrawal of the rejection of claim 1 and dependent claims 2-6 and 8-12.

Claims 7 and 24-27 have been cancelled, thus mooted the rejection of those claims.

**Claim Rejections over von Weissenfluh**

Claims 1, 13, 16, 17, and 26 have been rejected under 35 U.S.C. §102(b) in view of von Weissenfluh, U.S. Patent No. 5,421,725 ("von Weissenfluh"). Claims 18, 24, 25, and 27 have been rejected under 35 U.S.C. §103(a) in view of von Weissenfluh.

Von Weissenfluh discusses a wedge shaped device for the fitting of a matrix to a tooth to be filled, including a portion made from a memory resin that is light activated. The wedge device is almost entirely a transparent wedge with a strip or insert of shape memory material for pressing the matrix against the tooth to be filled. Again, von Weissenfluh discusses holding a matrix tightly against a tooth during a dental filling procedure, which is very different from separating teeth. There is no orthodontic use taught by the reference.

Claim 1 recites an orthodontic separator, wherein said separator is in the shape of an o-ring or dog bone. The importance of such a shape is described above. As stated, von Weissenfluh only uses a wedge shape, and does not teach, describe, or suggest an o-ring or dog bone. Thus, claim 1 is both novel and nonobvious over von Weissenfluh. Therefore, applicants respectfully request withdrawal of the rejection of independent claim 1, and dependent claims 13, 16, 17, and 18.

Claims 13 and 16 have been amended, and depend from claim 1. Claim 33 has been added. Support for these amendments may be found in the original claims and through the specification. Support for claim 13 may be found, for example, at page 5, lines 17-25 and page 6, line 23 – page 7, line 3. Support for claim 16, for example, may be found at page 4, lines 24-28, and page 5, lines 17-25. Support for claim 33 may be found, for example, at page 3, line 27 – page 4, line 23. In addition, claim 17 has been amended, and support for the amendment may be found, for example, in the original claims, and at page 3, line 21 – page 4, line 5.

Claims 24-27 have been cancelled, mooted the rejection of those claims.

Claims 14-15 have been rejected under 35 U.S.C. §103(a) in view of von Weissenfluh and Langer et al., U.S. Patent No. 6,388,043 ("Langer").

Von Weissenfluh discusses a wedge with a shape memory insert or strip. Langer discusses shape memory alloys and shape memory polymers. Example materials include sutures, screws, plates, tubes, splints, etc.

Claim 14 has been amended and recites a separator comprising a shape memory metal alloy, wherein said separator is in the shape of a coil or washer. Support for the amendment to claim 14 may be found, for example, at page 4, line 24 – page 5, line 16. The usefulness of such shapes is discussed in the attached declaration in paragraphs 11 and 12. These shapes allow a contracted metal alloy shape to be easily inserted between adjacent teeth. Upon activation, the shape expands in such a way as to increase the compressive force between the teeth, and do so in a manner that maintains the separator in the proper location for the required time, and allows the separator to distribute the compressive force over a larger area of the tooth than just a single contact point. Neither von Weissenfluh nor Langer disclose, teach, or suggest an orthodontic separator wherein the separator comprises a metal alloy in the shape of a coil or washer. Therefore, claim 14 is nonobvious over the cited references, and applicants respectfully request the withdrawal of the rejection of independent claim 14 and dependent claim 15.

Claims 21-22 have been rejected under 35 U.S.C. §103(a) in view of von Weissenfluh and Langer.

Claim 21 has been amended and recites an orthodontic separator consisting essentially of a shape memory material. Support for the amendment to claim 21 may be found, for example, at page 4, line 24 – page 5, line 16, and FIGs. 2-3. Von Weissenfluh discusses a wedge with a shape memory insert or strip. The shape memory portion is only a small portion of the entire wedge used. The majority of the wedge is made from a non-shape memory, transparent resin material. Adding the heat activated material of Langer does not change the proportions of the components. Therefore, claim 21 is nonobvious over the cited references, and applicants respectfully request the withdrawal of the rejection of independent claim 21 and dependent claim 22.

**New Claims**

Claims 28-33 are new. Support for claim 28 may be found in the original claims and throughout the specification. Support for claims 29-30 may be found, for example, at page 4, line 24 – page 5, line 16. Support for claims 31-32 may be found in the original claims and throughout the specification. Support for new claim 33 is discussed above.

**Claim Objections**

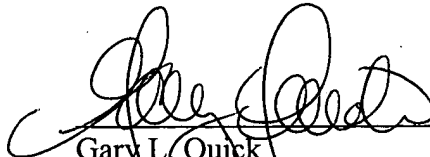
Claims 19, 20, and 23 have been objected to, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims.

Claim 20 has been amended to correct the dependency due to the amendment to claim 17, and claim 20 now depends upon claim 28. In view of the amendments and arguments discussed above, no other changes to claims 19, 20, or 23 will be made at this time.

Applicants request entry of the amendments and reconsideration of the claims. The Examiner is invited to contact the undersigned if it would be helpful for prosecution of this matter. Enclosed is a \$120.00 check for the Petition for Extension of Time fee. As 6 claims have been cancelled and 6 claims added, no additional claim fees are believed to be due. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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Gary L. Quick  
Reg. No. 55,553

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696